Complete Summary

GUIDELINE TITLE

Procedure guideline for C-14 urea breath test.

BIBLIOGRAPHIC SOURCE(S)

Society of Nuclear Medicine. Procedure guideline for C-14 urea breath test. Reston (VA): Society of Nuclear Medicine; 2001 Jun 23. 6 p. (Society of Nuclear Medicine procedure guidelines; no. 3.0).

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Helicobacter pylori gastrointestinal infection
- Chronic gastritis
- Peptic ulcer disease
- Gastric cancers (e.g., adenocarcinoma of the stomach, lymphoma)

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Nuclear Medicine
Radiology

INTENDED USERS

Allied Health Personnel
Physicians

GUIDELINE OBJECTIVE(S)

To assist nuclear medicine practitioners in recommending, performing, interpreting and reporting the results of the C-14 urea breath test

TARGET POPULATION

- Patients with duodenal ulcers following anti-Helicobacter pylori therapy, to document eradication
- Patients with or suspected of having non-non-steroidal anti-inflammatory drug (NSAID)-induced gastric ulcers, for initial diagnosis or follow-up

INTERVENTIONS AND PRACTICES CONSIDERED

C-14 urea breath test

MAJOR OUTCOMES CONSIDERED

Sensitivity and specificity of C-14 urea breath test

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Relevant guidelines from other organizations were reviewed and taken into consideration. Literature searches were performed to include current scientific evidence. In addition, references known to experts and references from the nuclear medicine community were considered.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Drafts of the guideline were submitted to members of the Guideline Development subcommittee (methodologists) and the Task Force (subject experts). These reviewers indicated on a line-by-line basis any suggestions or recommendations for the revision of the guideline. The percentage of agreement for all reviewers was calculated for each revision and compiled by the Society of Nuclear Medicine (SNM) central office. It is expected that the percentage of agreement will increase with each revision.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

When the Task Force and Guideline Development Subcommittee completed their edits, draft procedure guidelines were distributed to the Society of Nuclear Medicine (SNM) Sample Review Group for comment. (The SNM Sample Review Group is a cross-section of approximately 100 nuclear medicine practitioners representing every field of specialization).

The guideline was approved by the SNM Commission on Health Care Policy, the Board of Directors, and the House of Delegates.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Background Information and Definitions

The presence of active Helicobacter pylori (HP) infection can be diagnosed non-invasively with the C-14 urea breath test (UBT). This test is based on the detection of the enzyme urease, produced by Helicobacter pylori. Since urease is not present in normal human tissues, and since other urease-producing bacteria do not colonize the stomach, the presence of urease in the stomach can be equated with Helicobacter pylori infection.

In the presence of urease, orally administered C-14 urea will be hydrolyzed into ammonia and $^{14}CO_2$. $^{14}CO_2$ is absorbed into the circulation and exhaled by the lungs. The presence of a significant amount of $^{14}CO_2$ in the exhaled breath indicates active Helicobacter pylori infection.

The C-14 urea breath test consists of the oral administration of C-14 urea, followed by sampling of the exhaled breath at timed intervals. The breath samples are then analyzed in a liquid scintillation counter.

Common Indications

Detection of the presence of Helicobacter pylori in the stomach.

- Given the very high probability of patients with duodenal ulcers (DU) being infected with Helicobacter pylori, the C-14 urea breath test has not been routinely recommended for initial diagnosis, but has been recommended to document Helicobacter pylori eradication following anti-Helicobacter pylori therapy. Eradication should be confirmed no sooner than 1 month, and preferably longer, after completion of therapy.
- Since the prevalence of Helicobacter pylori in gastric ulcer (GU) patients (non-nonsteroidal anti-inflammatory drug [NSAID]-induced gastric ulcers) is about 80%, the C-14–urea breath test may be used for initial diagnosis as well as follow-up in this patient subset.

Procedure

The detailed procedure recommendations in the guideline address the following areas: patient preparation; information pertinent to performing the procedure (i.e., important data that the physician should have about the patient at the time the exam is performed and interpreted); precautions; information regarding the radiopharmaceutical (i.e., ranges of administered activity, organ receiving the largest radiation dose, effective dose), image acquisition; interventions; processing; interpretation/reporting; quality control, and sources of error.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence for the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The intent of the procedure guideline is to describe the C-14 urea breath test in order to maximize the diagnostic information obtained in the study while minimizing the resources that are expended.

POTENTIAL HARMS

False positives and false negatives associated with the C-14 urea breath test.

Causes of potential false-negative results:

- Antibiotics (if administered within 30 days of the test)
- Bismuth (if administered within 30 days of the test)
- Sucralfate (if administered within 14 days of the test)
- Proton pump inhibitors (e.g. omeprazole [Prilosec™], lansoprazole [Prevacid™]) if administered within 14 days of the test
- Non-fasting
- Resective gastric surgery
- Difficulty with swallowing test capsule (additional breath samples collected at 15 or even 20 minutes post administered activity may be helpful)

Causes of potential false-positive results:

- Resective gastric surgery with potential resultant bacterial overgrowth (non-Helicobacter pylori urease)
- Achlorhydria

QUALIFYING STATEMENTS

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The Society of Nuclear Medicine has written and approved guidelines to promote the cost-effective use of high quality nuclear medicine procedures. These generic recommendations cannot be applied to all patients in all practice settings. The guidelines should not be deemed inclusive of all proper procedures or exclusive of other procedures reasonably directed to obtaining the same results. The spectrum of patients seen in a specialized practice setting may be quite different than the spectrum of patients seen in a more general practice setting. The appropriateness of a procedure will depend in part on the prevalence of disease in the patient

population. In addition, the resources available to care for patients may vary greatly from one medical facility to another. For these reasons, guidelines cannot be rigidly applied.

Advances in medicine occur at a rapid rate. The date of a guideline should always be considered in determining its current applicability.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Society of Nuclear Medicine. Procedure guideline for C-14 urea breath test. Reston (VA): Society of Nuclear Medicine; 2001 Jun 23. 6 p. (Society of Nuclear Medicine procedure guidelines; no. 3.0).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Jun (updated 2001 Jun 23)

GUIDELINE DEVELOPER(S)

Society of Nuclear Medicine, Inc - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of Nuclear Medicine (SNM)

GUIDELINE COMMITTEE

Guideline Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Helena R. Balon, MD (William Beaumont Hospital, Royal Oak, MI); Eileen Roff, RN, MSA (William Beaumont Hospital, Royal Oak, MI); John E. Freitas, MD (St. Joseph Mercy Hospital, Ann Arbor, MI); Vanessa Gates, MS (William Beaumont Hospital, Royal Oak, MI); Howard J. Dworkin, MD (William Beaumont Hospital, Royal Oak, MI).

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. This guideline updates a previously released version: Procedure guideline for C-14 urea breath test. Reston (VA): Society of Nuclear Medicine; 1998 Jun. 13 p. (Society of Nuclear Medicine Procedure Guidelines; version 2.0).

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Society of Nuclear Medicine (SNM) Web site.

Print copies: Available from SNM, Division of Health Care Policy, 1850 Samuel Morse Dr, Reston, VA 20190-5316; Phone: 1-800-513-6853 or 1-703-326-1186; Fax: 703-708-9015; E-Mail: ServiceCenter@snm.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Society of Nuclear Medicine. Procedure guideline for guideline development. Reston (VA): Society of Nuclear Medicine; 2001 Jun (version 3.0).

  Electronic copies: Available from the Society of Nuclear Medicine Web site.

- Society of Nuclear Medicine. Performance and responsibility guidelines for NMT. Reston (VA): Society of Nuclear Medicine; 2003.

  Electronic copies: Available from the Society of Nuclear Medicine Web site.

Print copies: Available from SNM, Division of Health Care Policy, 1850 Samuel Morse Dr, Reston, VA 20190-5316; Phone: 1-800-513-6853 or 1-703-326-1186; Fax: 703-708-9015; E-Mail: ServiceCenter@snm.org.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 20, 1999. It was verified by the guideline developer as of May 26, 1999. This updated summary was completed by ECRI on November 17, 2001. It was verified by the guideline developer as of November 27, 2001.

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